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TVFC and ASN Provider Biological Reports

Denise Starkey, MPH, MA
Vaccine Operations Group
Immunization Unit

Overview

- Monthly Report Validation (Due 5th of each month):
  - QA Process
    - Temperature Recording Form (EC-105)
      - Temperature excursion form
    - Vaccine Loss Report (if applicable)
    - Received Vaccine Orders (if applicable)
    - TVFC Vaccine Transfers Form (EC-67) (if applicable)
    - TVFC Vaccine Borrowing Form (EF11-14171) (if applicable)
    - Doses Administered Report
    - Monthly Biological Report (C-33)

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QA Process

Monthly Biological Reports

- Monthly vaccine management and reporting is required in Electronic Vaccine Inventory (EVI) system regardless of whether an order is submitted or not.

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Temperature Recording Form

Temperature Recording Form (EC-105), including:

- Refrigerator Fahrenheit (EC-105RF);
- Refrigerator Celsius (EC-105RC);
- Freezer Fahrenheit (EC-105FF);
- Freezer Celsius (EC-105FC);

Validate fields are legible and complete on <u>all pages</u>:

1. Month/Year
2. VFC PIN
3. Facility Name
4. TVFC Coordinator

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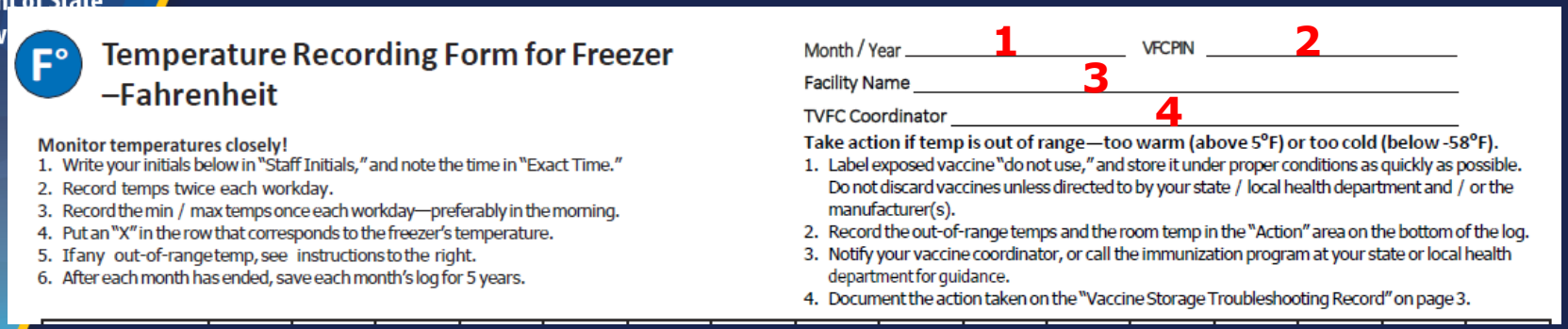


Temperature Recording Form for Freezer –Fahrenheit

Month / Year 1 VFCPIN 2

Facility Name 3

TVFC Coordinator 4

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min / max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

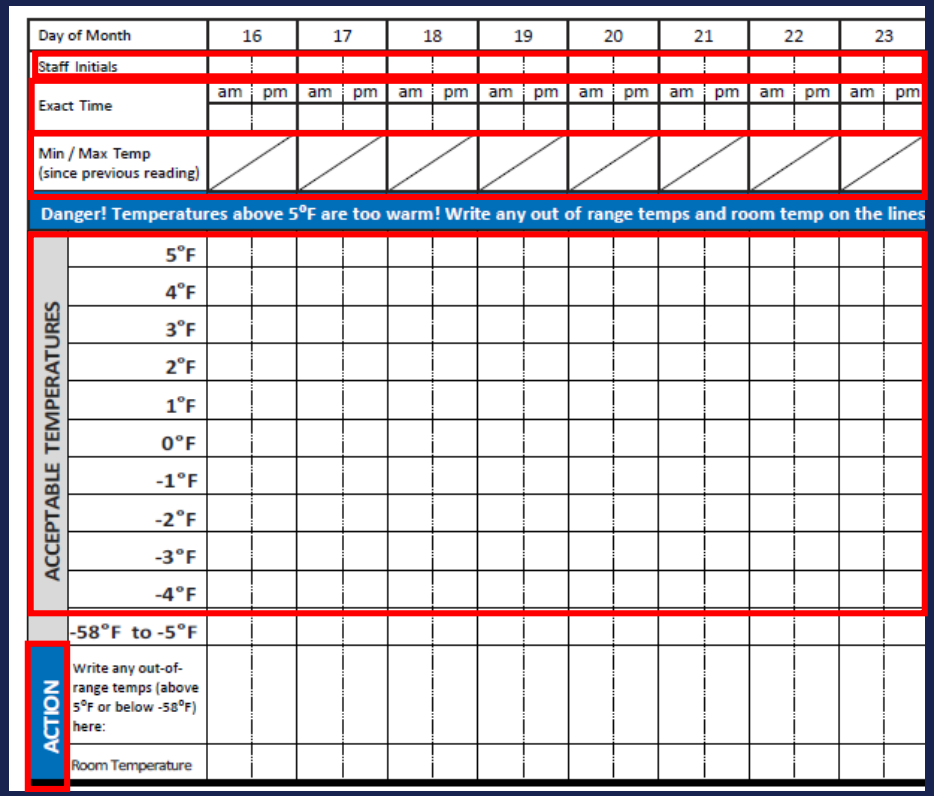
Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state / local health department and / or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Temperature Recording Form

Validate fields are legible and complete:

- Staff initials
- Exact time
- Min/Max Temp
- Acceptable temperatures
- Action for any out of range temps (if needed)



Day of Month	16		17		18		19		20		21		22		23	
Staff Initials																
Exact Time	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
Min / Max Temp (since previous reading)																

Danger! Temperatures above 5°F are too warm! Write any out of range temps and room temp on the lines

ACCEPTABLE TEMPERATURES																	
5°F																	
4°F																	
3°F																	
2°F																	
1°F																	
0°F																	
-1°F																	
-2°F																	
-3°F																	
-4°F																	
-58°F to -5°F																	
ACTION: Write any out-of-range temps (above 5°F or below -58°F) here:																	
Room Temperature																	

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Temperature Recording Form

Temperature Excursion Form (EC-105 Page 3)

- All fields must be complete:
  - PIN
  - Designate refrigerator or freezer
  - Date & time of event
  - Storage unit temperature
    - Temp when discovered
    - Min/Max temp
  - Room temperature
  - Person Completing Report (name, title, date)
  - Description of event
  - Action taken
  - Results

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Temperature Excursion Form Example (Complete)

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☑ Freezer

[redacted]

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered		Room Temperature at the time the problem was discovered	Person Completing Report	
Date: 12/19/2017	Temp when discovered: 8.4 F		Temp when discovered: 71°F	Name: [redacted]	
Time: 9:23 am	Minimum temp: -12 F°	Maximum temp: 9 F	Comment (optional):	Title: Medical Assistant	Date: 12/19/2017

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (36° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and / or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

12/19/17 Freezer unit sustained a temperature excursion during the TVFC compliance site visit with Patricia Parker, RN. Initial review of freezer at 9:23am revealed the Freezer temp was out of range at 8.4 deg F. At 9:35am, the freezer temp was 5.0 deg F. The lenght of time between the event and last documented reading was 15 minutes. The vaccines that were affected belonged to VFC Stock. The inventory were Varimax and Proquad, all manufactured by Merck. The list included 20 Proquad Lot# N022472 Exp. 2/19/19, 20 Proquad Lot# N021725 Exp. 2/6/19, 10 Proquad Lot# N019826 Exp. 1/9/19, 20 Varimax Lot# M027346 Exp. 6/1/18 & 22 Varimax Lot# M037643 Exp 9/1/18. At the time of the event we had frozen water bottles & frozen coolant packs.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state / local health department and / or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state / local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

At the time of the event, the affected vaccines were labeled with a "do not use" sign. Right after that I contacted Merck the vaccine manufacturer. I talked to the vaccine medical team and informed them of the incident. Now we are making sure that every person that administers vaccines is closing the doors properly and be more careful about monitoring temperatures.

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state / local health department instructions for vaccine disposition.)

Based on Merks temperature guidelines, the vaccines were viable and good to use.
Refer to Case #00690006.

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Stock No. EC-105RF
Revised 11/2016

Temperature Excursion Form Example (Incomplete)

Vaccine Storage Troubleshooting Record (check one) ☒ Refrigerator ☐ Freezer [redacted]

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event (If multiple, related events occurred, see Description of Event below.)	Storage Unit Temperature (at the time the problem was discovered)		Room Temperature (at the time the problem was discovered)	Person Completing Report	
Date: 6/5/17	Temp when discovered: 51.8		Temp when discovered: 70	Name: [redacted]	
Time: 10:00am	Minimum temp:	Maximum temp:	Comment (optional):	Title: Medical Asst	Date: 6/5/17

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (36° to 46°F (2° to 8°C) for refrigerator; -58° to 5°F (-50° to -15°C) for freezer)
- Inventory of affected vaccines [illegible] VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, [illegible] for example, were [illegible] the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, [illegible] vaccine)
- Include any other information you feel [illegible] understanding [illegible]

Had a site visit - discovered temp reading was not read correctly according to mininum and max temp.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state / local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Local health Dept.
manufacturers were contacted
Make sure all temps are read correctly and documented

Results

- [illegible] for public/purchase vaccine [illegible] disposition?

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Temperature Excursion

Temperature Excursion Process

Ensure provider is following steps below:

- Place vaccines in a Vaccine Quarantine Bag and label vaccines as “DO NOT USE”
- Store vaccines in a unit where they can be kept under appropriate conditions
- Generate a report from the data logger
- Contact:
  - Vaccine manufacturer, obtain documentation for the viability of the vaccine
  - Responsible Entity to report the manufacturer’s vaccine viability determination

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Temperature Excursion

Temperature Excursion Process

Ensure provider is following steps below:

- Complete the Vaccine Storage Troubleshooting Record attached to the Temperature Recording Form.
- Request a new temperature log showing in-range temperatures
- Review manufacturer reports with provider

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Vaccine Loss

(if applicable)

Policy:

- Vaccine loss must be documented on a Vaccine Loss Report (VLR) electronically in EVI no later than four days past the date of the expiration or incident(s).

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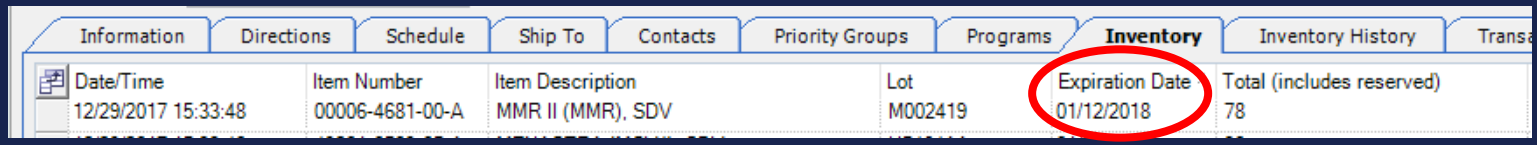
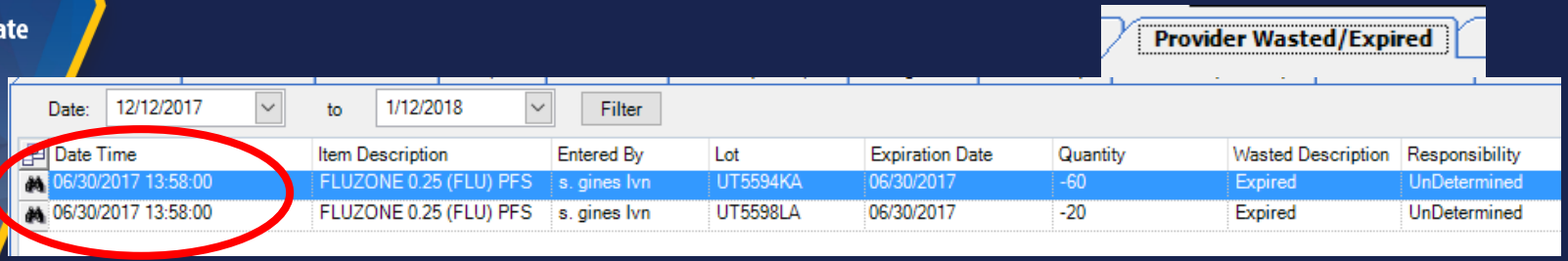
Vaccine Loss
(if applicable)

QA Process:

- Check for expired vaccine
  ITEAMS Inventory Tab



- Check for vaccine loss report submission
  ITEAMS Provider Wasted/Expired Tab



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Vaccine Loss

(if applicable)

QA Process:

- If expired vaccines found in inventory:
  - Contact provider and provide education
    - Remove expired vaccine from inventory.
    - Have the provider complete the vaccine loss report in EVI.
  - Ensure documentation for vaccine loss is submitted to the responsible entity.
  - Responsible entity sends the signed vaccine loss report via email to: VLR@dshs.texas.gov.
  - Follow-up with provider until VLR is received.

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Receive Vaccine Orders
(if applicable)

QA Process: ITEAMS

- Confirm vaccine orders are received in the Past Orders tab:
  - If vaccine orders are in Shipped or Packed status:
  - Check progress of the vaccine order:
    1. Click Past Order tab
    2. Double click on order line item
    3. Click on Order Header Inquiry
    4. Click on Customer Dispute
       - View Date/Time and Transaction Name column to see updates

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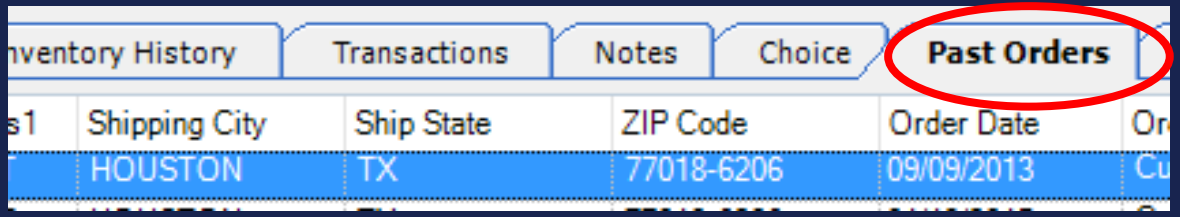
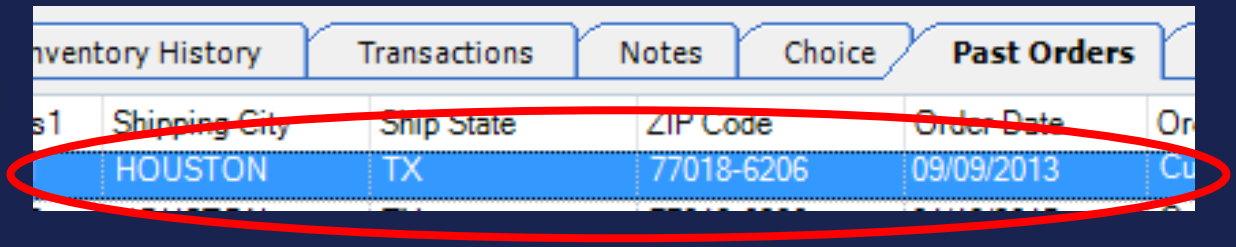
Receive Vaccine Orders
(if applicable)

QA Process: ITEAMS

1. Click Past Order tab



2. Double click on order line item



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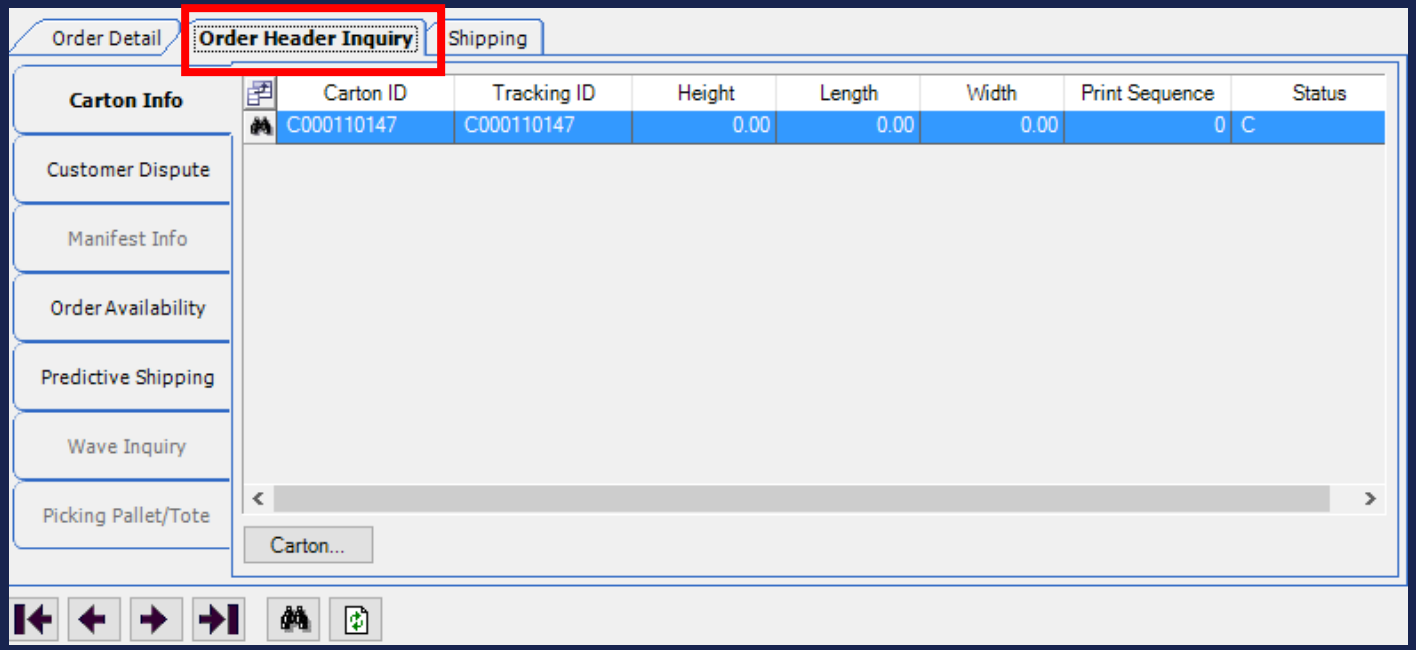
Receive Vaccine Orders
(if applicable)

QA Process: ITEAMS

3. Click on Order Header Inquiry:



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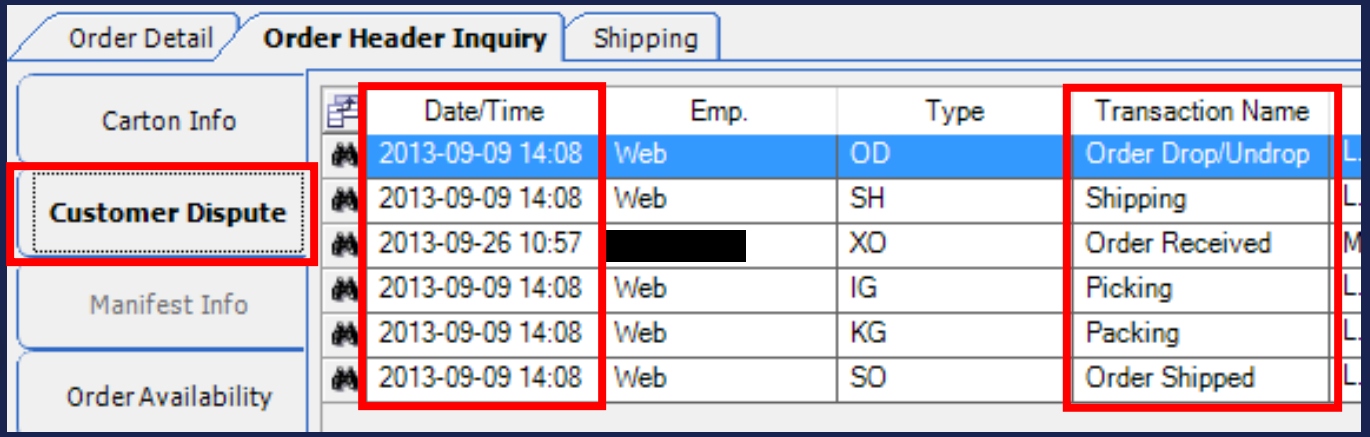
Receive Vaccine Orders
(if applicable)

QA Process: ITEAMS

4. Click on Customer Dispute
    - View Date/Time and Transaction Name column to see updates



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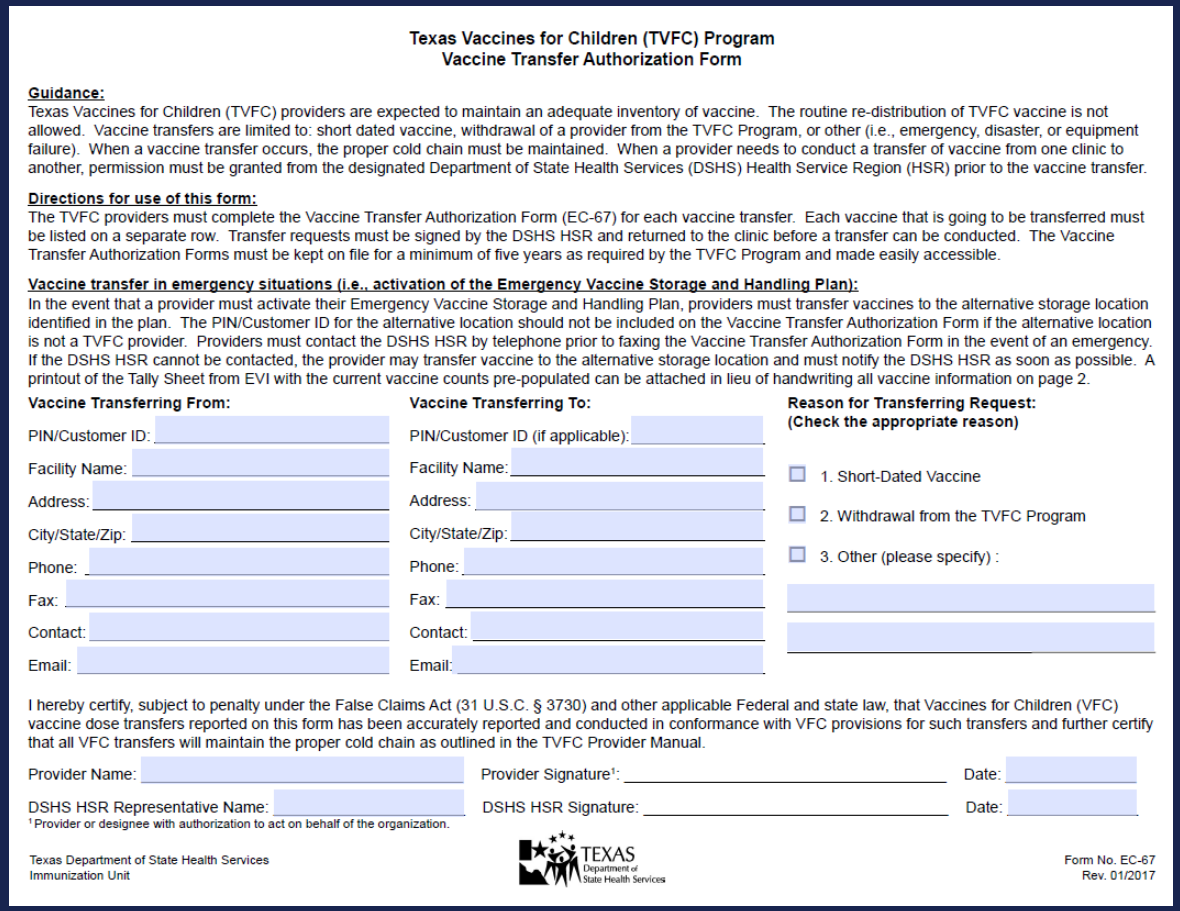
Vaccine Transfers

(if applicable)

QA Process:

- All vaccine transfer forms must be complete and received.



Texas Vaccines for Children (TVFC) Program
Vaccine Transfer Authorization Form

Guidance:
Texas Vaccines for Children (TVFC) providers are expected to maintain an adequate inventory of vaccine. The routine re-distribution of TVFC vaccine is not allowed. Vaccine transfers are limited to: short dated vaccine, withdrawal of a provider from the TVFC Program, or other (i.e., emergency, disaster, or equipment failure). When a vaccine transfer occurs, the proper cold chain must be maintained. When a provider needs to conduct a transfer of vaccine from one clinic to another, permission must be granted from the designated Department of State Health Services (DSHS) Health Service Region (HSR) prior to the vaccine transfer.

Directions for use of this form:
The TVFC providers must complete the Vaccine Transfer Authorization Form (EC-67) for each vaccine transfer. Each vaccine that is going to be transferred must be listed on a separate row. Transfer requests must be signed by the DSHS HSR and returned to the clinic before a transfer can be conducted. The Vaccine Transfer Authorization Forms must be kept on file for a minimum of five years as required by the TVFC Program and made easily accessible.

Vaccine transfer in emergency situations (i.e., activation of the Emergency Vaccine Storage and Handling Plan):
In the event that a provider must activate their Emergency Vaccine Storage and Handling Plan, providers must transfer vaccines to the alternative storage location identified in the plan. The PIN/Customer ID for the alternative location should not be included on the Vaccine Transfer Authorization Form if the alternative location is not a TVFC provider. Providers must contact the DSHS HSR by telephone prior to faxing the Vaccine Transfer Authorization Form in the event of an emergency. If the DSHS HSR cannot be contacted, the provider may transfer vaccine to the alternative storage location and must notify the DSHS HSR as soon as possible. A printout of the Tally Sheet from EVI with the current vaccine counts pre-populated can be attached in lieu of handwriting all vaccine information on page 2.

Vaccine Transferring From:
PIN/Customer ID:
Facility Name:
Address:
City/State/Zip:
Phone:
Fax:
Contact:
Email:

Vaccine Transferring To:
PIN/Customer ID (if applicable):
Facility Name:
Address:
City/State/Zip:
Phone:
Fax:
Contact:
Email:

Reason for Transferring Request:
(Check the appropriate reason)
☐ 1. Short-Dated Vaccine
☐ 2. Withdrawal from the TVFC Program
☐ 3. Other (please specify) :

I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that Vaccines for Children (VFC) vaccine dose transfers reported on this form has been accurately reported and conducted in conformance with VFC provisions for such transfers and further certify that all VFC transfers will maintain the proper cold chain as outlined in the TVFC Provider Manual.

Provider Name: Provider Signature[1]: Date:
DSHS HSR Representative Name: DSHS HSR Signature: Date:
[1] Provider or designee with authorization to act on behalf of the organization.

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Immunization Unit

Form No. EC-67
Rev. 01/2017

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Vaccine Transfers

(if applicable)

QA Process:

- Ensure all fields are complete:

TVFC Vaccine Transfer Authorization Form

Vaccine Type:	National Drug Code (NDC):	Lot Number:	Expiration:	Dose Quantity:

- All vaccine transfers MUST be approved by DSHS HSR.

The routine re-distribution of TVFC vaccine is not allowed.

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Vaccine Borrowing

(if applicable)

Policy:

Vaccine borrowing is the utilization of TVFC vaccines as a replacement system for filling the vaccine needs of non-TVFC eligible patients.

- Educate provider about borrowing policies.
- All vaccine borrowing documentation MUST be submitted to the responsible entity **within 24 hours**.
- Follow-up with the provider until all vaccine doses are replaced and accounted.
- Keep documentation for 5 years.

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Vaccine Borrowing

(if applicable)

QA Process:

- All vaccine borrowing forms must be complete and received **within 24 hours.**

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Facility Name:

Pin #:

TVFC VACCINE BORROWING REPORT

All TVFC providers are expected to manage and maintain an adequate inventory of vaccine for both their TVFC and non-TVFC-eligible patients. Vaccine supplied by the TVFC Program cannot be provided to a non-TVFC-eligible patient. **Planned borrowing of TVFC vaccine including the use of TVFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.** Undocumented borrowing and administering of TVFC vaccines to a non-TVFC patient is considered fraud.

TVFC providers cannot use TVFC vaccine as a replacement system for filling the vaccine needs of a non-TVFC privately insured patient. If a TVFC dose(s) is accidentally administered to a non-TVFC-eligible patient, the provider must complete the TVFC Borrowing Report and replace the vaccine immediately.

COMPLETE THIS FORM WHEN:

- A dose of TVFC vaccine is administered to a non TVFC-eligible child.
- A dose of privately-purchased vaccine is administered to a TVFC-eligible child.

HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed.
- The provider must sign and date at the bottom of this report.
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7 Other or 13 Other) is entered in the Vaccine Borrowing Reportable.

Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing TVFC Dose	Code		Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time / delay in shipping)	1		TVFC vaccine shipment delay (order placed on time / delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2		TVFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3		Ran out of TVFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with TVFC dose	4		Short-dated TVFC dose was exchanged with private dose	11
Accidental use of TVFC dose for a private patient	5		Accidental use of a Private dose for a TVFC-eligible patient	12
Replacement of Private dose with TVFC when insurance plan did not cover vaccine	6		Other – Describe:	13 Other
Other – Describe:	7 Other			

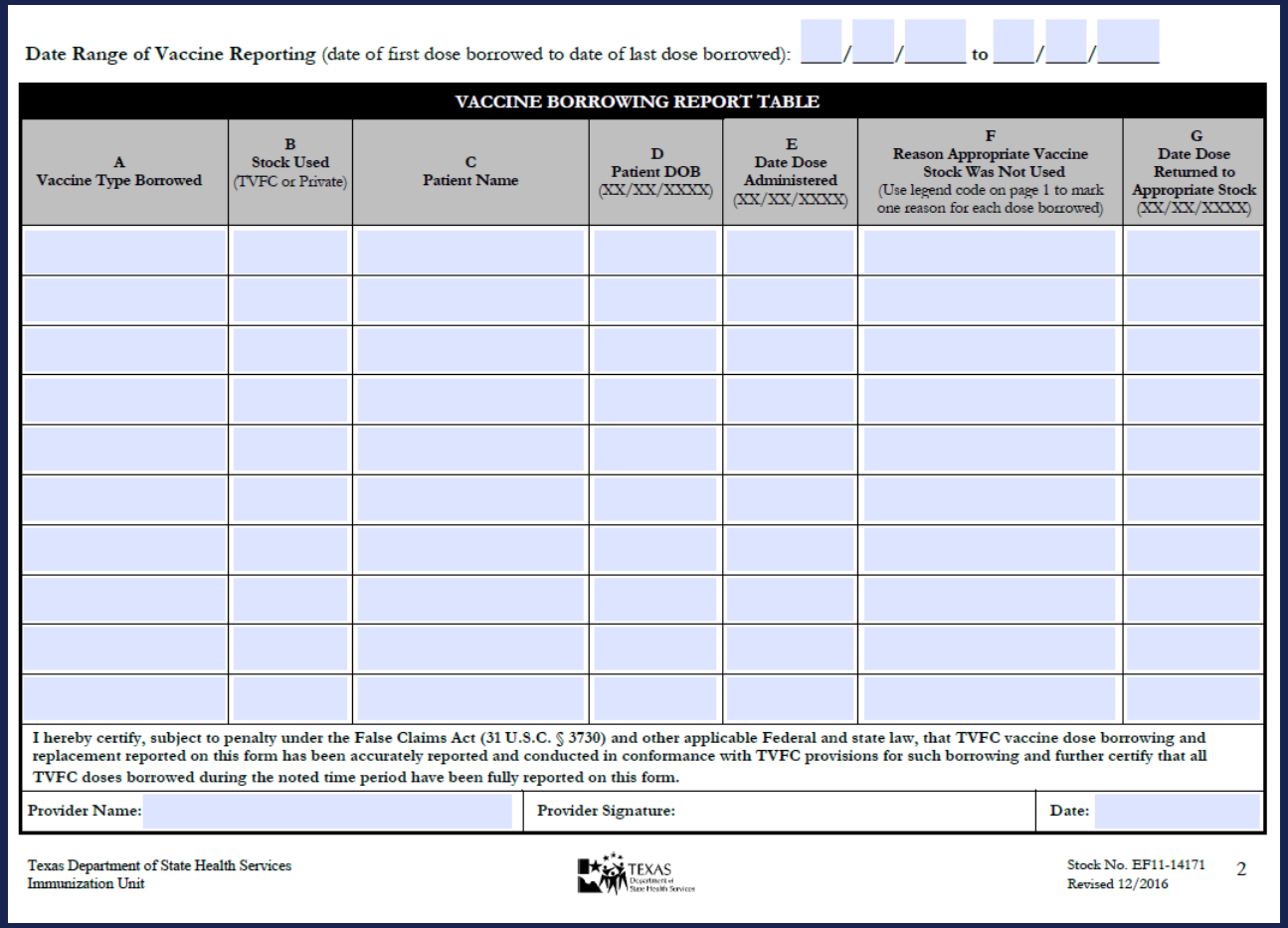
WHAT TO DO WITH THIS FORM:

- The Vaccine Borrowing Form must be kept as part of the TVFC Program records for a minimum five years and be made easily available.

Vaccine Borrowing
(if applicable)

QA Process:

- Ensure all fields are complete:



Date Range of Vaccine Reporting (date of first dose borrowed to date of last dose borrowed): ___/___/_____ to ___/___/_____

VACCINE BORROWING REPORT TABLE

A Vaccine Type Borrowed	B Stock Used (TVFC or Private)	C Patient Name	D Patient DOB (XX/XX/XXXX)	E Date Dose Administered (XX/XX/XXXX)	F Reason Appropriate Vaccine Stock Was Not Used (Use legend code on page 1 to mark one reason for each dose borrowed)	G Date Dose Returned to Appropriate Stock (XX/XX/XXXX)

I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that TVFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with TVFC provisions for such borrowing and further certify that all TVFC doses borrowed during the noted time period have been fully reported on this form.

Provider Name:	Provider Signature:	Date:

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Immunization Unit

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Stock No. EF11-14171
Revised 12/2016

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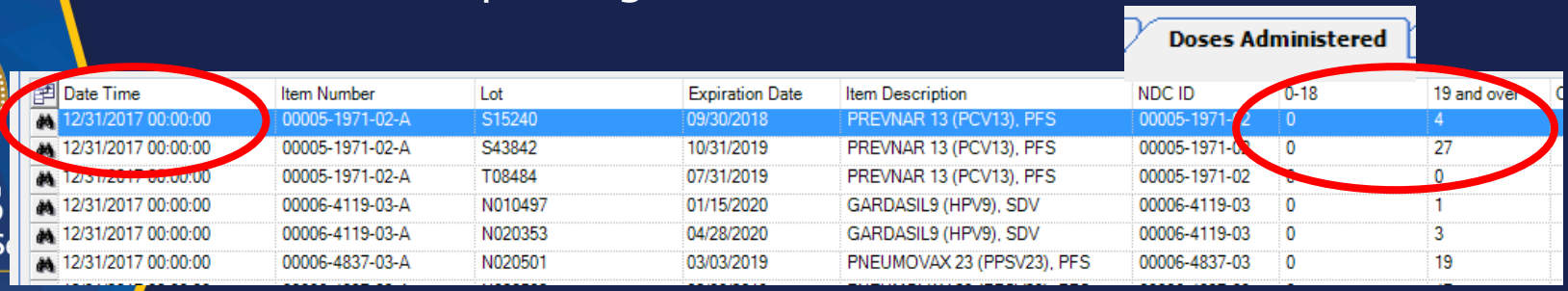
Doses Administered

QA Process: ITEAMS

- Doses Administered tab:
  - Verify report was completed
    - Check the Date/Time column to confirm reporting month.



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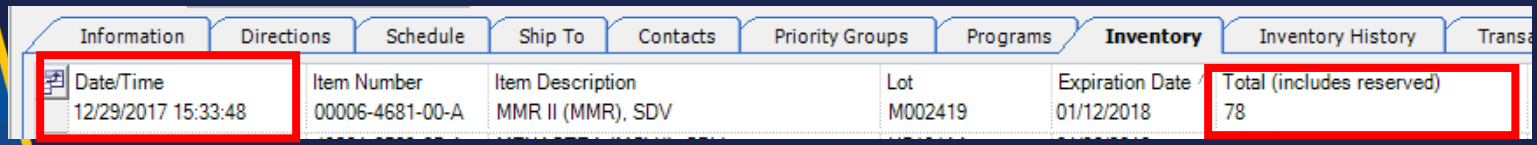
Monthly Biological Report (C-33)

QA Process: ITEAMS

- Physical inventory count
- Check for report submission date
- Confirm there are not negative values present in the "Total (includes reserved)" column



- If negative values are found, contact provider to correct errors:
  - Doses administered not reported for current/previous month (correct EVI Doses Administered History)
  - Miscount of current inventory (correct EVI C-33)

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Other QA Options

QA Process: ITEAMS

- Transactions tab:

  Verify doses administered and vaccine inventory report were submitted
  - Date/Time column to confirm submission
  - Transaction Type Description

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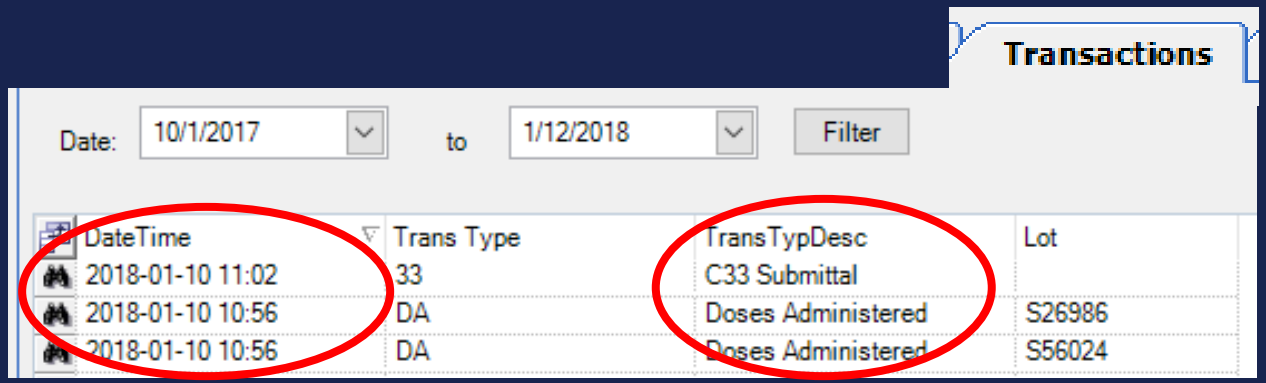

Summary

Provider Manual Policy:

On the 5th of each month, the following documents must be completed and submitted to the Responsible Entity.

- Temperature Recording Form (EC-105)
- Vaccine Loss Report (if applicable)
- TVFC Vaccine Borrowing Form (if applicable)
- Monthly Biological Report (C-33)
- Any other reports or required documents

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Questions?

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Thank you!

Denise Starkey, MPH, MA

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